

Overview of routine tests for adventitious agents

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The safety and purity of biological products and the biological starting materials used to manufacture them are assessed by performing tests for adventitious agents (inadvertent microbial contaminants). The speaker will provide an overview of the routine or conventional tests that are currently in use, in order to provide a frame-work for discussion of new test methods that will be the subject of later presentations in the conference. The routine adventitious agent testing includes tests for bacteria and fungi, mycoplasmas and spiroplasmas, mycobacteria, and viruses. The viral tests include both *in vivo* and *in vitro* methods. The test methods will be briefly reviewed. Breadth and sensitivity of these methods will be discussed, including the gaps in knowledge in this regard. Methods to prevent contamination with transmissible spongiform encephalopathy agents will also be described.